

Notice of Allowability

Application No.

09/542,445

Examiner

S. Devi, Ph.D.

Applicant(s)

STAPLES ET AL.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Applicants' Brief filed 09/09/04.
2. ☒ The allowed claim(s) ~~is~~ are claims 1-3.
3. ☐ The drawings filed on _____ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____ |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input checked="" type="checkbox"/> Other <u>Attachment</u> . |

ATTACHMENT TO NOTICE OF ALLOWABILITY

Examiner's Amendment

1) An Examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to Applicants, an amendment may be filed as provided by 37 C.F.R. 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee. The authorization to prepare this Examiner's amendment was provided by Ms. Cynthia Tymeson via lines 3-7 on page 2 of Applicants' amendment filed 01/02/02.

Accordingly, this application has been amended as indicated below:

In line 4 of page 27 and at # 18 of the Table on page 27; and lines 3 and 23 of page 28 of the specification, the limitation 'Pluronic' has been replaced with the limitation --Pluronic®--.

Applicants' Response

2) Acknowledgment is made of Applicants' response submitted via the Appeal Brief filed 09/09/04. The arguments therein have been fully considered. See paragraph 4 below.

Status of Claims

3) Claims 1-3 are pending and are under examination.

Rejection(s) Withdrawn

4) The rejection of claims 1-3 made in paragraph 10 of the Office Action mailed 12/31/02 and maintained in paragraph 9 of the Office Action under 35 U.S.C § 103(a) as being unpatentable over Tabachnick *et al.* (*Arch. Biochem. Biophys.* 136: 467-479, 1970) in view of Khanna *et al.* (US 4,798,804, already of record), is withdrawn in light of Applicants' new arguments submitted via the Appeal Brief. Applicants argue that although Tabachnick used several benzoic acid derivatives, some of which are ortho-substituted, Tabachnick does not teach the usefulness of any ortho-substituted benzoate containing an alkyl or ortho-substituted derivatives as releasing agents. Applicants submit that neither Table IV, Figure 5, nor the pages referenced in the Office Action contain any benzoate substituted with CH₃ or recommend using an ortho substituted benzoate containing an alkyl. With regard to Khanna, Applicants state that Khanna does not disclose methoxybenzoic acid for releasing endogenous proteins from ligands; instead Khanna discloses a process to determine the presence of digoxin with a first step of binding digoxin to cyclodextrin, a carbohydrate, and then releasing the cyclodextrin from the digoxin using methoxybenzoic acid.

Applicants contend that there is no suggestion in Khanna that the methoxybenzoic acid releasing agent would work for complexes other than cyclodextrin: digoxin such a complex that includes endogenous proteins.

Remarks

- 5) Claims 1-3 are allowed.
- 6) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The RightFax number for submission of amendments, responses or papers is (703) 872-9306.
- 7) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.Mov>. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).
- 8) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (571) 272-0864.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

November, 2004


S. DEVI, PH.D.
PRIMARY EXAMINER

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Approved
James C. House

JAMES HOUSEL
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600